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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/734,564	12/12/2003	Jon H. Astle	1657/2012	2507

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EXAMINER	
GODDARD, LAURA B	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 05/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/734,564	ASTLE ET AL.	
	Examiner	Art Unit	
	Laura B. Goddard, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) *12-28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/26/04,8/19/04* .
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The Election filed March 31, 2006 in response to the Office Action of December 1, 2005 is acknowledged. Applicant elected with traverse Group I, claims 1-11 and species of colon cancer-specific marker SEQ ID NO:72. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP 818.03(a)).

Claims 1-28 are pending. Claims 12-28 are withdrawn from further consideration by the examiner under 35 CFR 1.142(b) as being drawn to non-elected inventions. Claims 1-11 are currently under prosecution.

Specification

2. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code on page 17. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent

granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1-6 and 8-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Oberg et al (Anticancer research, 2000, 20:1085-91).

The claims are drawn to a method of diagnosing colon cancer in an individual comprising obtaining a serum sample from said individual, detecting the presence of TIMP 1, wherein the step of detecting comprises contacting a serum sample with an antibody which is capable of binding to TIMP 1 (claims 1-3), and a method of diagnosing colon cancer in an individual comprising detecting the presence of TIMP 1 and at least one other colon cancer specific marker in said sample, wherein the step of detecting comprises contacting a serum sample with a fist antibody that binds to TIMP 1 and a second antibody that binds to the at least one other colon cancer specific marker (claims 6, 8, 9), wherein the antibodies are labeled (claims 4 and 10), and wherein the individual is human (claims 5 and 11).

Oberg et al teach a method of diagnosing colon cancer in an individual comprising obtaining a serum sample from said individual, detecting the presence of TIMP 1, and wherein the step of detecting comprises contacting a serum sample with a monoclonal antibody which is capable of binding to TIMP 1 in an ELISA (p. 1086, col. 2). Oberg et al teach that patients with colorectal cancer had, compared to the control group, significantly high levels of TIMP 1 (p. 1088, col. 1; p. 1089, col. 1). Oberg et al further teach said method of diagnosing colon cancer comprising detecting additional colon cancer-specific markers MMP-2, MMP-9, and TIMP-2 using antibodies in an

ELISA (abstract) and that levels of MMP-2, MMP-9, and TIMP-2 were significantly higher in colon cancer patients than in the control group (p. 1088, col. 1; col. 1; p. 1089, col. 1). Hence, all of the limitations of the claimed methods are met.

4. Claims 1-5 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent Application 2004/0105862 A1, Pan et al, filed 4/24/2002, published 6/3/2004.

The claims are drawn to a method of diagnosing colon cancer in an individual comprising obtaining a serum sample from said individual, detecting the presence of TIMP 1, wherein the step of detecting comprises contacting a serum sample with an antibody which is capable of binding to TIMP 1 (claims 1-3), wherein the antibodies are labeled (claim 4), and wherein the individual is human (claim 5).

Pan et al teach a method for diagnosing colon cancer comprising detecting human TIMP-1 in a serum sample using a TIMP-1 antibody, wherein the antibody comprises a detectable label (abstract, [0036-0037], [0098-0099]).

5. Claims 1-6 and 8-11 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent Application 2003/0082652 A1, Holten-Andersen et al, filed 4/8/2002, published 5/1/2003.

The claims are drawn to a method of diagnosing colon cancer in an individual comprising obtaining a serum sample from said individual, detecting the presence of TIMP 1, wherein the step of detecting comprises contacting a serum sample with an

antibody which is capable of binding to TIMP 1 (claims 1-3), and a method of diagnosing colon cancer in an individual comprising detecting the presence of TIMP 1 and at least one other colon cancer specific marker in said sample, wherein the step of detecting comprises contacting a serum sample with a fist antibody that binds to TIMP 1 and a second antibody that binds to the at least one other colon cancer specific marker (claims 6, 8, 9), wherein the antibodies are labeled (claims 4 and 10), and wherein the individual is human (claims 5 and 11).

Holten-Andersen et al teach a method for diagnosing colon cancer in a human comprising detecting TIMP-1 in serum samples using an ELISA with TIMP-1 antibodies ([0003], [0010], Example 1, Example 4). Holten-Andersen et al teach said method of diagnosing colon cancer further comprising determining the concentration of a second colon cancer tumor marker in the serum sample, wherein the second tumor marker was CEA measured using a CEA EIA kit ([0044], Example 6, Example 16). Holten-Andersen et al teach that by adding an additional marker, an improvement in the diagnostic sensitivity of total TIMP-1 can be obtained, while maintaining a high specificity of 98%. Thus the combination of CEA and TIMP-1 could be useful as a screening procedure to identify patients with a high risk of having colon cancer ([0226]).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent Application 2003/0082652 A1, Holten-Andersen et al, filed 4/8/2002, published 5/1/2003 in view of Schrewe et al (Molecular and Cellular Biology, 1990, 10:2738-2748) (see sequence search result #1 in both PIR 80 and UniProt databases for SEQ ID NO:72 search).

The claims are drawn to a method of diagnosing colon cancer in an individual comprising detecting the presence of TIMP 1 and at least one other colon cancer specific marker in a serum sample (claim 6), wherein said at least colon cancer specific marker is SEQ ID NO:72 (claim 7).

Holten-Andersen et al teach a method for diagnosing colon cancer in a human comprising detecting TIMP-1 and a second colon cancer tumor marker in serum samples wherein the second tumor marker was CEA measured using a CEA EIA kit ([0003], [0010], Example 1, Example 4, [0044], Example 6, Example 16). Holten-Andersen et al teach that by adding an additional marker, an improvement in the diagnostic sensitivity of total TIMP-1 can be obtained, while maintaining a high specificity of 98%. Thus the combination of CEA and TIMP-1 could be useful as a screening procedure to identify patients with a high risk of having colon cancer ([0226]). Holten-Andersen et al does not teach that the second tumor marker is SEQ ID NO:72.

Schrewe et al teach that CEA is a widely used tumor marker, especially in the surveillance of colonic cancer patients (abstract). Schrewe et al teach the CEA colon cancer marker with 100% homology to SEQ ID NO:72 of the instant application (see

sequence search result #1 in both PIR 80 and UniProt databases for SEQ ID NO:72 search).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to detect the presence of CEA colon cancer tumor marker consisting of SEQ ID NO:72 in the method taught by Holten-Andersen et al because Schrewe et al teach teaches that SEQ ID NO:72, or CEA, is a widely used tumor marker for colon cancer. One would have been motivated to detect SEQ ID NO:72 as a second tumor marker in the method of Holten-Andersen et al because both references teach that CEA is used as a tumor marker for colon cancer, hence one of ordinary skill in the art would have a reasonable expectation of success in detecting SEQ ID NO:72 in addition to TIMP-1 in order to diagnose colon cancer.

7. **Conclusion:** No claims are allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura B. Goddard, Ph.D. whose telephone number is (571) 272-8788. The examiner can normally be reached on 8:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Laura B Goddard, Ph.D.
Examiner
Art Unit 1642

JEFFREY SIEW
SUPERVISORY PATENT EXAMINER